Appendix 9

Dermatest Pty Ltd

Certificate

Product:	Sunscreen	Our Reference:	99040
Batch No:	KB/069/2175/000/25		
Client:	Ego Pharmaceuticals	No. of Test Subjects:	10

The above product was evaluated for Sun Protection Factor (SPF) according to the procedures specified in Australian/New Zealand Standard 2604- 1998.

After testing for 40 mins, a Water Resistance SPF value of 32 was obtained and this classifies the product as a Very High Protection Sunscreen. Based on the results, the maximum water resistance time which can be claimed is 40 mins .

A full record of the procedure and related documentation is retained on file in our laboratory.

Date 6/9/99 Signed

24 King St, Rockdale
N.S.W. Australia 2216
ACN 079 987 698

Phone Lab: 61 2 95563835
Phone Office: 61 2 95562601
Fax: 61 2 95563361

REPORT OF EVALUATION OF SUN PROTECTION PRODUCT

. ›jective:

This panel was convened to evaluate the effectiveness of a test material as a sunscreen product by determining he Sun Protection Factor (SPF) on human skin as described in AS/NZS 2604:1998 , using a xenon arc solar imulator as the UV source.

‘. Sample Description:

On 17/6/99 a sample labelled Sunscreen KB/069/2175/000/25 was received from Ego Pharmaceuticals and assigned a Dermatest Reference No. 99040

3. Test Material Handling

The record of the sample was entered into a log identifying the lot number, sample description, batch number, sponsor, date received and tests requested. Samples are retained for a period of two years beyond final report generation.

4. Standard for Inclusion of a Panelist in a Study

4.1 Individuals eighteen years of age or older.
4.2 Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the investigator.
4.3 Individuals who have completed a preliminary medical history evaluation.
4.4 Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing.
4.5 Individuals with no known abnormal response to sunlight.

5. Standard for Exclusion of a Panelist from a Study

4. Individuals taking medication which in the opinion of the investigator would mask or interfere with the results.
4.2. Individuals with chronic skin allergies.
4.3. Individuals with suntan or sunburn.
4.4. Individuals with abnormal reaction to the sun.
4.5. Pregnant or lactating females.

6. Informed Consent and Medical History Forms

An informed consent was obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Panelists signed and dated the informed consent document to indicate their authorisation to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms, are available for inspection only on the premises of Dermatest Pty Ltd and during normal office hours.

7. Panel Composition:

Healthy volunteers over the age of 18 years were recruited for this study. The panel consisted of fair skin individuals with skin types I, II or III defined as follows:

Type I Always burns easily; never tans (sensitive)
Type II Always burns easily; tans minimally (sensitive)
Type III Burns moderately; tans gradually (light brown - normal)

8. ıstitutional Ethics Committee (IEC).

The IEC of Dermatest Pty Ltd, consists of 5 or more individuals, chosen in accordance with ICH Guidelines for Good Clinical Practice. The list of IEC members is kept on file at Dermatest Pty Ltd, and is available for inspection on the premises during normal office hours.

9. Solar Simulation

The light source employed is a 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 16S or Model 601) having a continuous emission spectrum in the UVB range from 290 to 320 nm. Xenon arc is selected on the basis of its black body radiation temperature of 6000°K which produces continuous UV spectra (all wavelengths) substantially equivalent to that of natural sunlight. This device is equipped with a dichroic mirror (which reflects all radiation below 400nm) and works in conjunction with a 1 mm thick Schott WG320 filter (which absorbs all radiation below 290nm) to produce simulation of the solar UVA©UVB spectrum. A 1 mm thick UG 5 or UG 11 filter (black lens) was added to remove reflected (infra-red, greater than 700 nm) heat and remaining visible radiation. UV radiation was monitored continuously during exposure using a Sunburn UV Meter/Dose Controller System (Solar Light Co) . Measurements were taken at a position within 8 mm from the surface of the skin. The field of irradiation was 1 cm in diameter. Realignment of the Light Sources and calibration of the sunburn metres are conducted annually by independent certification facilities and more often as necessary at the discretion of the operating technician.

10. Determination of the Static Sun Protection Factor (Where conducted)

The procedure for this study is outlined in Australian/New Zealand Standard AS/NZS 2604:1998 One test site area served to determine each subject's Minimal Erythema Dose (MED). This was executed by exposing the back to a series of timed incremental UV exposures at 25% intervals. The individual subject's MED is the shortest time of exposure that produces minimally perceptible erythema at 16 to 24 hours post irradiation. Th ‘est area is described as the infrascapular area of the back to the right and left of the midline. The ap_r .opriate Reference Sunscreen Product was delivered to the test site through plastic volumetric syringes. The material was evenly applied to a rectangular area for a final covering of 2.0 mg/cm^2.

Fifteen minutes after application, a series of UV light exposures in 25% increments calculated from previously determined MED's bracketing the expected SPF were administered from the solar simulator to subsites within the treated area. On the actual day of testing another series of exposures was administered to an adjacent untreated site of unprotected skin to redetermine the MED. An adjacent test site was then selected to perform a static determination on the test substance.

11. Determination of Water Resistance (Where Conducted)

This test is employed to determine the substantivity of a test product and its ability to resist water immersion. The procedure was as outlined in section 9 above, and the procedure described in Appendix D4 of AS 2604 followed.The immersion schedule is listed as follows:

10.1 Subject immersed in the Spa pool for 20 min with 4 min of air agitation

10.2 5 minutes rest period out of the water.This sequence was repeated for the required time period.

Immersion was achieved indoors in a circulating whirlpool tub from a 1 h.p. pump at 3450 RPM delivering 8 g.p.m. through 1.5 cm diameter ports. The water was maintained at an average temperature of 33°C+/-2°C. The pH of the water was maintained between 6.8 and 7.2.

The test area was air dried prior to exposure from the solar simulator using 25% increments. The exact series of exposures given was determined by the control MED and the expected SPF of the product.

12. Evaluation of Response
The volunteers are instructed to return to the testing facility sixteen to twenty four hours post exposure, for evaluation of delayed erythemic response. The smallest exposure or the least amount of energy required to produce erythema (MED) in the treated site was recorded. The SPF was then calculated by the equation: MED Protected Skin / MED Unprotected Skin = SPF Factor.

13. Colour Discrimination Test
All technical employees of Dermatest Pty Ltd are required to take and pass a visual colour discrimination examination using the Farnsworth-Munsell 100 Hue Test.

14. Rejection Criteria
Panelist's results were rejected and the panelist replaced if:
8.1. The responses on the treated test site were randomly absent or out of sequence. This was an indication that the products were not spread uniformly.
8.2. An MED could not be obtained due to elicited response at all exposure sites.
8.3. The exposure series failed to elicit an MED response on either the untreated or the applied skin areas. The test was then considered a technical failure and the subject's data was discarded.

15. Individual Panelist Results
These are set out in the attached report.

16. Observations
No adverse effects or unexpected reactions of any kind were observed on any of the subjects.

17. Archiving: All original samples, raw data sheets, technicians notebooks, correspondence files and copies of final reports and remaining specimens are maintained on premises of Dermatest Pty Ltd in limited access storage files. A duplicate disk copy of final reports is archived separately off site.